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Docket No.: K-C 19204

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Hoa La WILHELM
Dave Allen SOERENS
Lee Delson WILHELM
James Hongxue WANG

Group No.: 1789

Serial No.: 10/683,789

Examiner: Melanie J. Yu

Filing Date: 10 October 2003

Title: WEARABLE ARTICLE WITH MULTI-LEVEL ALERT SYSTEM

Confirmation No.: 1789

Customer No.: 35844

RESPONSE TO ORDER RETURNING UNDOCKETED APPEAL TO EXAMINER

Mail Stop Appeal Brief - Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Order Returning Undocketed Appeal To Examiner dated 10 March 2006, enclosed is a Supplemental Appeal Brief including an Appendix B (Evidence) and Appendix C (Related Proceedings).

I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on

17 March 2006

17 March 2006
Date

Maxwell J. Petersen
Signature

Appendix B includes only the prior art relied upon by the Examiner. Appendix C is empty. There are no related proceedings.

In a telephone conversation with Examiner Yu on 15 March 2006, Applicants' attorney agreed to submit the Supplemental Appeal Brief without waiting for written notification from the Examiner.

Respectfully submitted,

Maxwell J. Petersen
Registration No. 32,772

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Confirmation No.: 1789

Customer No.: 35844

SUPPLEMENTAL APPEAL BRIEF UNDER 37 C.F.R. §41.37

Mail Stop Appeal Brief - Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Applicants herewith file their Appeal Brief in the above-identified case, pursuant to their Notice of Appeal filed 04 May 2005.

1. REAL PARTY IN INTEREST

The real party in interest is Kimberly-Clark Worldwide, Inc., the assignee of the present application (as recorded at reel 014594, frame 0378).

I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on

17 March 2006

17 March 2006 — Maxwell J Petersen
Date — Signature

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2. RELATED APPEALS AND INTERFERENCES

Applicants are not aware of any related appeals or interferences with regard to the present application.

3. STATUS OF CLAIMS

Claims 1, 3-26 and 28 are pending in the application. The present Appeal is directed to Claims 1, 3-26 and 28, which were finally rejected in an Office Action mailed 09 February 2005.

4. STATUS OF AMENDMENTS

All Amendments filed thus far have been entered.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a wearable article equipped with a multi-level alert system for detecting two or more levels of a mammalian substance in a mammalian extract. Independent Claims 1, 10, 20 and 28 all require that the wearable article comprises a substrate, and a target area on the substrate including first and second sub-areas for receiving a mammalian extract.

Claim 1 further requires a chemical detection system on the target area for detecting at least a first lower level of the mammalian substance in the first sub-area and a second higher level of the mammalian substance in the second sub-area. The chemical detection system comprises a first chemical composition on the first sub-area and a second chemical composition on the second sub-area. The first chemical composition detects the first lower level of the mammalian substance and the second chemical composition detects the second higher level of the mammalian substance.

Claim 1 further requires that the mammalian substance being detected is not a hydrogen ion or ion aggregate. This limitation is intended to distinguish the invention from the use of conventional pH-measuring devices which detect different levels of hydrogen ion concentration.

Claim 10 further requires a chemical detection system on the target area which initiates a first signal in response to a first level of the mammalian substance in the first sub-area and a second signal in response to a second level of the mammalian substance in the second sub-area. The chemical detection system comprises a first chemical composition on the first sub-area and a second chemical composition on the second sub-area. The first chemical composition detects the first lower level of the mammalian substance and the second chemical composition detects the second higher level of the mammalian substance. Claim 10 further requires that the mammalian substance being detected is not a hydrogen ion or ion aggregate.

Claim 20 requires the target area to include first, second and third sub-areas. A first chemical composition on the first sub-area detects a first level of the mammalian substance. A second chemical composition on the second sub-area detects a second level of the mammalian substance. A third chemical composition on the third sub-area detects a third level of the mammalian substance. Again, the mammalian substance being detected is not a hydrogen ion or ion aggregate.

Claim 28 further requires a first chemical composition on the first sub-area which emits a first signal in response to a first level of the mammalian substance, and a second chemical composition on the second sub-area which emits a second signal in response to the first level of the mammalian substance. The first and second signals can be compared to quantify the first level of the mammalian substance. Again, the mammalian substance being detected is not a hydrogen ion or ion aggregate.

The wearable article of the invention is useful for detecting different levels of mammalian substances. The mammalian substance can be any substance not normally found in a mammalian extract, or abnormal levels of any substance which is normally present. Examples include nitrites, leucocytes, glucose, ketones, blood, phenylanaline, bilirubin, urobilinogen, protein, albumin, specific enzymes, and drugs (See page 2, lines 8-13). The only type of mammalian substances excluded by the claims are hydrogen ions and ion aggregates, which can be detected at different levels using pH paper and other pH detection devices.

In an early Amendment filed 08 December 2004, Applicants attempted to avoid the negative claim limitation by presenting a Markush group for Claims 1, 10, 20 and 28 which recited all of the mammalian substances listed on page 2, lines 8-13 of the specification, except for hydrogen ions and ion aggregates. Applicants were advised in a subsequent telephone interview that such an Amendment might result in a twelve-way restriction requirement between all of the Markush elements. Accordingly, Applicants filed a Supplemental Amendment on 28 January 2005 deleting the Markush group from Claims 1, 10, 20 and 28, and adding the negative claim limitation. Under these circumstances, the negative claim limitation was the only avenue available for Applicants to seek meaningful patent protection based on the filing fees already paid.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1, 3-26 and 28 stand rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement.

B. Claims 1, 3-11, 14-20, 22-26 and 28 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Publication 2003/015830 ("Diehl et al.") in view of an article entitled "Critical Revision of Presumptive Tests for Bloodstains," Forensic Science Communications, Vol. 1, No. 2, July 1999 ("Ponce et al."), and further in view of U.S. Patent 3,917,452 (Rittersdorf et al.)

C. Claims 10, 12, 13, 20 and 21 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent 6,617,488 ("Springer et al.") in view of Ponce et al. and Rittersdorf et al.

7. ARGUMENT

A. The Rejection of Claims 1, 3-26 And 28 Under 35 U.S.C. §112 Should Be Reversed

The Examiner rejected Claims 1, 3-26 and 28 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Independent Claims 1, 10, 20 and 28 provide a negative limitation excluding a hydrogen ion or ion aggregate from the mammalian substance to be detected. The specification on page 2, lines 8-13 discloses a hydrogen ion or ion aggregate as a mammalian substance capable of being detected, and does not expressly exclude these substances. According to the Examiner, the claims are therefore not adequately described.

The claims originally presented in the patent application did not limit the type of mammalian substance being detected. In response to claim rejections based on the prior art, Applicants initially amended the independent claims to recite that the mammalian substance:

> ...comprises a substance selected from the group consisting of nitrites, leucocytes, glucose, ketones, blood, phenylanaline, bilirubin, urobilinogen, protein, albumin, specific enzymes, and drugs and combinations thereof. See Amendment filed 08 December 2004.

The foregoing amendment narrowed the scope of the claims. Subsequently, to avoid a multiple restriction requirement, Applicants further amended the independent claims to delete the Markush group and instead recite:

> ... the mammalian substance being detected is not a hydrogen ion or ion aggregate. See Amendment filed 28 January 2005.

The Examiner's position that the claims are not supported by the specification is contrary to MPEP 2173.05(i) which states, in pertinent part:

> Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In Re Johnson, 558 F. 2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("The specification, having described the whole, necessarily described the part remaining").

In the present case, Applicants' specification plainly describes the invention in a non-limiting fashion, i.e., as not being limited to the detection of any particular mammalian substance(s):

> The mammalian substance being detected may be any substance not normally found in a particular mammalian extract, or abnormal levels of any substance typically found in a mammalian extract at a normal level (p. 2, lines 8-10).

Accordingly, the specification provides descriptive support for claims which are not limited to any particular mammalian substance(s). Additionally, the specification explicitly describes fourteen exemplary mammalian substances which may be detected (p. 2, lines 10-13). Under these circumstances, Applicants are entitled to exclude from the claims, by way of negative limitation, any one or more of the mammalian substances that are positively recited in the specification. MPEP 2173.05(i).

Hydrogen ions and ion aggregates are among the mammalian substances that are positively recited in the specification. Therefore, they may be explicitly excluded from the claims. The specification, having described the "whole" inventive concept (not limited to any particular mammalian substance(s)) necessarily describes the part remaining after the exclusion of hydrogen ions and ion aggregates. In Re Johnson, Id.

In an Advisory Action dated 05 April 2005, the Examiner argues that In Re Johnson does not apply because the claims in that case excluded a species from a genus. However, the decision in In Re Johnson is not limited to the exclusion of a species from a well-defined genus. Instead of basing its decision on a defined genus-species relationship, the court in In Re Johnson emphasized consideration of the specification as a whole and the right of Applicants to claim less than the full scope of the disclosure:

> The present specification includes broad statements such as: "Any electron withdrawing group can be employed as the activator group in these compounds." The specification also discusses preferred embodiments, alternative embodiments, and the practical limits of operation...
>
> While the Board found that "no antecedent basis exists in the parent case" for the "limited genus" in Claim 1, we see more than ample basis for claims of such scope... Two of the many choices for E and E′ precursor compounds are deleted from the protection sought because appellant is claiming less than the full scope of his disclosure. 194 USPQ at 195.

Furthermore, subsequent decisions have found negative claim limitations to be supported by the specification even where the negative limitations were not directed to a species, and there was no genus. In Ex Parte Parks, 30 USPQ 2d 1234, 1236 (BPAI, 1993), the Board stated:

> The Examiner contends that the rejected claims lack adequate descriptive support because there is "no literal basis for the" claim limitation "in the absence of a catalyst." Clearly, the observation of a lack of literal support does not, in and of itself, establish a prima facie case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. §112...
>
> In the situation before us, it cannot be said that the originally filed disclosure would not have conveyed to one having ordinary skill in the art that appellants had possession of the concept of conducting the decomposition step generating nitric acid in the absence of a catalyst...30 USPQ 2d at 1236.
>
> Accordingly, the Examiner's rejection of Claims 1 through 10, 20 through 22 and 55 through 80 under the first paragraph of 35 U.S.C. §112 for lack of descriptive support is reversed. 30 USPQ 2d at 1237.

In the present case, as in In Re Johnson, the specification provides explicit descriptive support for the claims without the negative limitation excluding hydrogen ions and ion aggregates from the mammalian substances being detected. The specification broadly indicates that the type of mammalian substance to be detected is not limited (p. 2, lines 8-10). As in In Re Johnson, Applicants introduced the negative limitation excluding two of the many embodiments of mammalian substances listed in the specification, in order to claim less than the full scope of the original disclosure. As in Ex Parte Parks, it is very clear from the specification that Applicants had possession of embodiments of the claimed invention, wherein the mammalian substance being detected is not a hydrogen ion or ion aggregate.

For these reasons, the rejection of Claims 1, 3-26 and 28 under 35 U.S.C. §112, first paragraph, should be reversed.

B. The Rejection Of Claims 1, 3-11, 14-20, 22-26 And 28 Under 35 U.S.C. §103(a) Should be Reversed

The Examiner rejected Claims 1, 3-11, 14-20, 22-26 and 28 under 35 U.S.C. §103(a) as obvious over Diehl et al. in view of Ponce et al. and Rittersdorf et al. This rejection should be reversed because the Examiner failed to establish a prima facie case of obviousness.

When claims have been rejected as obvious in view of a combination of prior art references, a proper analysis under 35 U.S.C. §103 requires inter alia consideration of two factors:

> 1) Whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process, and
>
> 2) Whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Both the suggestion and the reasonable expectation of success must be found in the prior art, and not in Applicants' disclosure. In Re Vaeck, 947 F. 2d 488, 20 USPQ 2d 1438, 1442 (Fed. Cir. 1991). The mere fact that the references can be combined does not render the combination obvious unless the prior art also suggests the desirability of the combination. In Re Mills, 916 F. 2d 680, 16 USPQ 2d 1430 (Fed. Cir. 1990). Furthermore, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In Re Gordon, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Finally, if the proposed combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In Re Ratti, 270 F. 2d 810, 123 USPQ 349 (CCPA 1959) (Claims are not obvious where the combination of references would require a substantial reconstruction and redesign of elements shown in the primary reference, and would change the basic principle under which the primary reference device was designed to operate).

Diehl et al. discloses a wearable article comprising a dehydration indicator adapted to measure a urine ionic strength correlated to a specific gravity of the wearer's urine and provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of specific gravity (Abstract). While the reference does not specifically mention the type of ions detected, it is known that the ions in urine include hydrogen ions, as well as ion aggregates (e.g., sodium chloride). From the examples, it is apparent that hydrogen ions (the concentration of which defines pH) are being detected. Other than by measuring the concentration of hydrogen ions, or ion aggregates such as sodium chloride, there is no disclosed alternative for measuring the ionic strength in urine. Thus, a fair reading of Diehl et al. would require the detection of hydrogen ions, and/or ion aggregates.

Applicants' Claims 1, 10, 20 and 28 preclude the detection of hydrogen ions, or ion aggregates. Yet the Examiner alleges that Ponce et al. (which teaches semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine and a third chemical composition comprising leucomalachite in order to test for false results in blood detection) can be incorporated into Diehl et al. to make Applicants' claimed invention. The Examiner further alleges that Rittersdorf et al. (which teaches the detection of blood in urine, feces and vomit) provides a motivation to combine Ponce et al. with Diehl et al. (28 January 2005 Office Action, p. 4). There is no explanation of how or where in Rittersdorf et al., a motivation to combine Ponce et al. with Diehl et al. can be derived.

Ponce et al. discloses chemical reagents useful for detecting blood in blood stains. Instead of detecting ions, the reagents function according to an oxidation-reduction reaction (p. 2). The Examiner has provided no explanation of how the reagents in Ponce et al. can be successfully employed in the dehydration indicator of Diehl et al.

The dehydration indicator in Diehl et al. operates by a) measuring a urine ionic strength, b) correlating the ionic strength of the specific gravity of a wearer's urine, and c) providing a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity (Abstract). The dehydration indicator typically changes color, or causes a color to appear or disappear, at a predetermined ionic strength (pp. 3-4, ¶¶26-29). The Examiner has provided no evidence or technical explanation of how the reagents in Ponce et al. can be employed to measure ionic strength or indicate dehydration as required by Diehl et al.

It is therefore apparent that the reagents disclosed in Ponce et al. cannot be substituted for the chemical compositions used to measure urine ionic strength in Diehl et al. without a) rendering Diehl et al. inoperable for its intended purposes of measuring ionic strength and dehydration of urine, and/or b) completely changing the principle of operation of the Diehl et al. dehydration indicator. However, the Office Action is not clear as to whether the Examiner proposes to substitute the chemical reagents of Ponce et al. for the chemical compositions in Diehl et al. or add the chemical reagents of Ponce et al. to the chemical compositions of Diehl et al.

If the reagents of Ponce et al. were instead added to the chemical compositions of Diehl et al., the dehydration indicator would be rendered inoperable for a different reason. As explained above, the chemical reagents disclosed in Ponce et al. are oxidation-reduction compositions (See Ponce et al., p. 2). These substances would inherently interact with hydrogen ions or ion aggregates present in urine so as to affect the pH which is measured by the dehydration indicator. Thus, if the oxidation-reduction compositions of Ponce et al. were added to the chemical compositions of Diehl et al., the dehydration indicator would not provide an accurate measurement of the ionic strength or level of dehydration in a wearer's urine.

At the very least, the inclusion of oxidation-reduction reagents of Ponce et al. would completely change the principle of operation of the dehydration indicator of Diehl et al. Regardless of whether the proposed modification would a) render the dehydration indicator of Diehl et al. inoperable, or b) change its principle of operation, or c) both, the references (Ponce et al. and Diehl et al.) cannot be combined to support an obviousness rejection. See MPEP 2143.01.

The Examiner cites Rittersdorf et al. as allegedly providing a motivation to combine Ponce et al. with Diehl et al. Rittersdorf et al. provides no such motivation. Furthermore, Rittersdorf et al. does not explain how such a combination could be made without a) rendering the dehydration indicator of Diehl et al. inoperable for its intended purpose and/or b) changing the principle of operation of the dehydration indicator.

Rittersdorf et al. discloses test strips for detecting peroxidatively active substances in body fluids (Abstract). Rittersdorf et al. discloses that a buffer agent is needed to control the pH of the body fluid, to prevent false results (Col. 3, lines 4-14). It should be apparent that if a buffer agent were added to urine, to control its pH, then it would no longer be possible to measure the dehydration of urine by measuring its ionic strength, as disclosed in Diehl et al.

In other words, reagents which detect peroxidatively active substances require pH control to avoid false results. Such pH control is completely incompatible with the dehydration indicator of Diehl et al., which requires an accurate measurement of urine ionic strength to determine a level of dehydration. Rittersdorf et al. thus teaches away from adding the reagents of Ponce et al. to the dehydration indicator of Diehl et al.

For these reasons, the primary reference (Diehl et al.) cannot be modified to incorporate the reagents of the secondary reference (Ponce et al.) as proposed by the Examiner.

On the other hand, even if the references could be combined as proposed by the Examiner, Applicants' claims would not be obvious. For instance, the Board may find (contrary to Applicants' position) that combining Diehl et al. with the reagents of Ponce et al. does not render the dehydration indicator of Diehl et al. inoperable for its intended purpose of measuring ionic strength in urine. Under this scenario, the modified dehydration indicator would still be able to detect hydrogen ions and/or ion aggregates.

Such a modified dehydration indicator would not render obvious Applicants' claims because the claims preclude the detection of hydrogen ions or ion aggregates.

For these reasons, the obviousness rejection of Claims 1, 3-11, 14-20, 22-26 and 28 should be reversed.

C. The Rejection Of Claims 10, 12, 13, 20 And 21 Under 35 U.S.C. §103(a) Should be Reversed

The Examiner rejected Claims 10, 12, 13, 20 and 21 under 35 U.S.C. §103(a) as obvious over Springer et al. in view of Ponce et al. and Rittersdorf et al. This rejection should be reversed because the Examiner failed to establish a prima facie case of obviousness. The pertinent case law, and standards for establishing a prima facie case, are set forth above.

Springer et al. discloses a method and apparatus for gauging pH levels in the interiors of absorbent articles (Abstract). A measurement of pH, by definition, requires a detection of hydrogen ion concentration. Accordingly, the method and apparatus of Springer et al. cannot be modified to preclude the detection of hydrogen ions. To do so would render the disclosed method and apparatus inoperable for their intended purpose, and/or substantially change their principle of operation. MPEP 2143.01; In Re Gordon, Id; In Re Ratti, Id.

Applicants' Claims 10 and 20 preclude the detection of hydrogen ions, or ion aggregates. Yet the Examiner alleges that Ponce et al. (which teaches semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine and a third chemical composition comprising leucomalachite in order to test for false results in blood detection) can be incorporated into Springer et al. to make Applicants' claimed invention. The Examiner further alleges that Rittersdorf et al. (which teaches the detection of blood in urine, feces and vomit) provides a motivation to combine Ponce et al. with Springer et al. (28 January 2005 Office Action, pp. 5-6). There is no explanation of how, or where in Rittersdorf et al., a motivation to combine Ponce et al. with Springer et al. can be derived.

As explained above, Ponce et al. discloses reagents useful for detecting blood in blood stains. Instead of detecting ions, the reagents function according to an oxidation-reduction reaction (p. 2). The Examiner has provided no evidence or technical explanation of how the reagents in Ponce et al. can be employed to measure pH as required by Springer et al.

It is therefore apparent that the reagents disclosed in Ponce et al. cannot be substituted for the chemical compositions used to measure pH in Springer et al. without a) rendering Springer et al. inoperable for its intended purpose of measuring pH, and/or b) completely changing the principle of operation of the Springer et al. pH indicator. However, the Office Action is not clear as to whether the Examiner proposes to substitute the chemical reagents of Ponce et al. for the chemical compositions in Springer et al. or add the chemical reagents of Ponce et al. to the chemical compositions of Springer et al.

If the reagents of Ponce et al. were instead added to the chemical compositions of Springer et al., the pH indicator would be rendered inoperable for a different reason. As explained above, the chemical reagents disclosed in Ponce et al. are oxidation-reduction compositions (See Ponce et al., p. 2). These substances would inherently interact with hydrogen ions so as to affect the pH which is measured by the pH indicator. Thus, if the oxidation-reduction compositions of Ponce et al. were added to the chemical compositions of Springer et al., the pH indicator would not provide an accurate measurement of the pH in a liquid insult.

At the very least, the inclusion of oxidation-reduction reagents of Ponce et al. would completely change the principle of operation of the pH indicator of Springer et al. Regardless of whether the proposed modification would a) render the pH indicator of Springer et al. inoperable, or b) change its principle of operation, or c) both, the references (Ponce et al. and Springer et al.) cannot be combined to support an obviousness rejection. See MPEP 2143.01.

The Examiner cites Rittersdorf et al. as allegedly providing a motivation to combine Ponce et al. with Springer et al. Rittersdorf et al. provides no such motivation. Furthermore, Rittersdorf et al. does not explain how such a combination could be made without a) rendering the pH indicator of Springer et al.

inoperable for its intended purpose and/or b) changing the principle of operation of the pH indicator.

For these reasons, the primary reference (Springer et al.) cannot be modified to incorporate the reagents of the secondary reference (Ponce et al.) as proposed by the Examiner.

On the other hand, even if the references could be combined as proposed by the Examiner, Applicants' claims would not be obvious. For instance, the Board may find (contrary to Applicants' position) that combining Springer et al. with the reagents of Ponce et al. does not render the pH indicator of Springer et al. inoperable for its intended purpose. Under this scenario, the pH indicator would still be able to detect hydrogen ions. Such a modified pH indicator would not render obvious Applicants' claims because the claims preclude the detection of hydrogen ions or ion aggregates.

For these reasons, the obviousness rejection of Claims 10, 12, 13, 20 and 21 should be reversed.

8. CONCLUSION

For the above reasons, Applicants respectfully submit that the rejections posed by the Examiner are improper as a matter of law and fact. Accordingly, Applicants respectfully request the Board reverse the rejection of Claims 1, 3-26, and 28.

A check for the fee required by 37 CFR 41.37(a)(2) and 37 CFR 41.20(b)(2), updated pursuant to the Fiscal Year 2005 Fee Schedule, in the amount of $500.00, is attached hereto. Please charge any additional amount owed, or credit any overpayment, to Deposit Account 19-3550.

Respectfully submitted,

Maxwell J. Petersen
Registration No. 32,772

The PTO did not receive the following listed item(s) check for $ 500.00

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APPENDIX A (CLAIMS)

1. A wearable article equipped with a multi-level alert system for detecting two or more levels of a mammalian substance in a mammalian extract, the wearable article comprising:

a substrate;

a target area on the substrate including first and second sub-areas for receiving the mammalian extract; and

a chemical detection system on the target area for detecting at least a first lower level of the mammalian substance in the first sub-area and a second higher level of the mammalian substance in the second sub-area;

wherein the chemical detection system comprises a first chemical composition on the first sub-area and a second chemical composition on the second sub-area, the first chemical composition detects the first lower level of the mammalian substance and the second chemical composition detects the second higher level of the mammalian substance; and

the mammalian substance being detected is not a hydrogen ion or ion aggregate.

3. The wearable article of Claim 1, wherein the first chemical composition emits a first color to indicate detection of the first lower level of the mammalian substance, and the second chemical composition emits a second color to indicate detection of the second higher level of the mammalian substance.

4. The wearable article of Claim 1, wherein the target area further comprises a third sub-area, and the chemical detection system further comprises a third chemical composition on the third sub-area for detecting a third level of the mammalian substance.

5. The wearable article of Claim 4, wherein the first chemical composition emits a first color to indicate detection of the first level of mammalian substance, the second chemical composition emits a second color to indicate detection of the second level of mammalian substance, and the third chemical composition emits a third color to indicate detection of the third level of mammalian substance.

6. The wearable article of Claim 1, wherein the wearable article is a personal care absorbent article.

7. The wearable article of Claim 1, wherein the wearable article is a medical absorbent article.

8. The wearable article of Claim 1, wherein the wearable article is an athletic absorbent article.

9. The wearable article of Claim 1, wherein the wearable article is a nonabsorbent article.

10. A wearable article equipped with a multi-level alert system for detecting two or more levels of a mammalian substance in a mammalian extract, the wearable article comprising:

a substrate;

a target area on the substrate including first and second sub-areas for receiving the mammalian extract; and

a chemical detection system on the target area which initiates a first signal in response to a first level of the mammalian substance in the first sub-area and a second signal in response to a second level of the mammalian substance in the second sub-area;

wherein the chemical detection system comprises a first chemical composition on the first sub-area and a second chemical composition on the second sub-area, the first chemical composition detects the first lower level of the mammalian substance and the second chemical composition detects the second higher level of the mammalian substance; and

the mammalian substance being detected is not a hydrogen ion or ion aggregate.

11. The wearable article of Claim 10, wherein the first signal comprises a first color change in the first sub-area and the second signal comprises a second color change in the second sub-area.

12. The wearable article of Claim 10, wherein the first signal comprises a first light and the second signal comprises a second light.

13. The wearable article of Claim 10, wherein the first signal comprises a first sound and the second signal comprises a second sound.

14. The wearable article of Claim 10, wherein the target area includes a third sub-area, and the chemical detection system initiates a third signal in response to a third level of mammalian substance in the third sub-area.

15. The wearable article of Claim 10, wherein the wearable article is a personal care absorbent article.

16. The wearable article of Claim 10, wherein the wearable article is a garment.

17. The wearable article of Claim 10, wherein the wearable article is a medical absorbent article.

18. The wearable article of Claim 10, wherein the wearable article is an article of clothing.

19. The wearable article of Claim 10, wherein the wearable article is a nonabsorbent article.

20. A wearable article equipped with a multi-level alert system for detecting three or more levels of a mammalian substance in a mammalian extract, the wearable article comprising:

a substrate;

a target area on the substrate including first, second and third sub-areas for receiving the mammalian extract;

a first chemical composition on the first sub-area, which detects a first level of the mammalian substance;

a second chemical composition on the second sub-area, which detects a second level of the mammalian substance; and

a third chemical composition on the third sub-area, which detects a third level of the mammalian substance;

wherein the mammalian substance being detected is not a hydrogen ion or ion aggregate.

21. The wearable article of Claim 20, wherein the first, second and third sub-areas comprise concentric shapes.

22. The wearable article of Claim 20, wherein the first, second and third sub-areas comprise stripes.

23. The wearable article of Claim 20, wherein the first, second and third sub-areas comprise adjacent shapes selected from the group consisting of squares, circles, rectangles, triangles, diamonds, and combinations thereof.

24. The wearable article of Claim 20, wherein the first, second and third sub-areas comprise numbers, symbols, letters or words.

25. The wearable article of Claim 20, wherein the first chemical composition comprises phenolphthalein, the second chemical composition comprises o-tolidine, and the third chemical composition comprises leucomalachite.

26. The wearable article of Claim 20, wherein the mammalian substance comprises blood, and the chemical compositions in the sub-areas are adapted to detect different levels of the blood.

28. A wearable article equipped with a multi-level alert system for detecting two or more levels of a mammalian substance in a mammalian extract comprising:

a substrate;

a target area on the substrate including first and second sub-areas for receiving the mammalian extract;

a first chemical composition on the first sub-area which emits a first signal in response to a first level of the mammalian substance; and

a second chemical composition on the second sub-area which emits a second signal in response to the first level of the mammalian substance;

wherein the first and second signals can be compared to quantify the first level of the mammalian substance; and

the mammalian substance being detected is not a hydrogen ion or ion aggregate.

APPENDIX B (EVIDENCE)

No evidence is submitted pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132. Copies of the following prior art relied upon by the Examiner are attached.

> U.S. Publication 1003/015830 ("Diehl et al."), entered in an Office Action dated 02 November 2004;
>
> U.S. Patent 6,617,488 ("Springer et al."), entered in an Office Action dated 02 November 2004;
>
> U.S. Patent 3,917,452 ("Rittersdorf et al."), entered in an Office Action dated 02 November 2004; and
>
> Article entitled "Critical Revision of Presumptive Tests for Bloodstains," Forensic Science Communications, Vol. 1, No. 2, July 1999 ("Ponce et al."), entered in an Office Action dated 02 November 2004.

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Critical Revision of Presumptive Tests for Bloodstains

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Introduction

Advances in the polymerase chain reaction-based (PCR-based) forensic nuclear DNA procedures allow analysis of bloodstains containing as little as 200 picograms (pg) of DNA. It is possible that a 25-µL bloodstain diluted to approximately 1:3500 would contain sufficient DNA for PCR-based analysis. The analysis of mitochondrial DNA (mtDNA) requires less template DNA.

To achieve this, preliminary steps in a bloodstain investigation should provide precise and reliable results. An inadequate interpretation of stains may invalidate a criminal investigation. Normally the stain investigation should follow these steps:

1. Visually examine the stain or substance. Ideally, the visual aspect of the bloodstain is sufficiently expressive to point toward certain conclusions. In the event of doubts, these may be resolved in subsequent stages.

2. Perform presumptive tests using chemical reagents. DNA typing can be performed on stains that have presumptively tested positive for the presence of blood and have a visual appearance of blood. Further serological examinations can be performed if sufficient material remains.

3. Perform confirmatory tests to determine if blood is present. Confirmatory tests are less sensitive than presumptive and species-origin tests. Therefore, it is possible to obtain a negative result for a confirmatory test in the presence of blood. Hence, a negative confirmatory test does not negate the presence of blood.

4. Employ a species-origin test, if sufficient material remains, to determine if a stain (which may or may not have tested positive for the confirmatory test) contains human protein.

5. Employ DNA analysis to determine the genotype and the gender of the bloodstain's donor.

As an example, a case presents a stain that is thought to be a bloodstain after visual inspection. Chemical tests are performed, and a negative result is obtained. An investigator would normally conclude that it is not a bloodstain or that only an imperceptible amount of blood is present. Therefore, Steps 4 and 5 would not be performed.

Our study questions the dependability usually attributed to presumptive tests. Throughout the process, we found that a stain that was clearly a bloodstain gave a negative result in the presumptive test. This result was obviously a false negative, a nonlegitimate negative that might have detained a perfectly viable and necessary investigation.

False positives in presumptive tests have been studied by a number of authors (Cox 1991; Culliford and Nickols 1964), but we found no studies that show experimental proof of obtaining false negatives. The first experiments we performed to study false negatives resulted in the affirmation that when lemon juice is added to a blood sample, its acid content may prevent the detection of a positive test result (Verdú Pascual and Gisbert Grifo 1995). Because we knew that the chemical process on which presumptive tests are based is an oxidation-reduction reaction in which a reagent (o-tolidine, tetramethylbenzidine, phenolphthalein, and leucomalachite green) is oxidized by hydrogen peroxide in the presence of peroxidases, we concluded that the substance capable of interfering in the test must be a reduction compound.

Given that the aim of our study was to demonstrate that reduction substances contaminating a bloodstain may prevent a positive test result from being observed, ascorbic acid was chosen as the substance to be used after the components of lemon juice were analyzed (Windholz et al. 1996). For this reaction, the reduction power of the contaminator had to be adequate, and the variations produced depended on the type of reagent used for the test (tolidine and phenolphthalein). Nevertheless, should this working hypothesis be confirmed, it can be concluded that all tests grouped as catalytic tests entail the possibility of producing false negatives. Our study focused on false negatives by applying the tolidine test on a bloodstain (Castelló 1997; Gisbert 1998).

The next step is to extend our study to other reagents used in presumptive tests. If the cause of the interference produced in the test proves correct, similar results using other reagents can be expected. We plan to continue seeking an explanation of interferences in the test reaction. In our initial study, however, the following aims were pursued:

- test that the addition of ascorbic acid to a bloodstain produces a false negative;
- determine the effect of the contaminant on the different sample types used (liquid, stain, and print);
- determine if false negatives are obtained regardless of the reagent employed, allowing for the possibility that false-negative results are caused by contamination; and
- evaluate possible differences in the results obtained using different reagents.

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Materials and Methods

Reagents
O-tolidine (Probus)
Tetramethylbenzidine (Probus)
Leucomalachite green (Merck)
Phenolphthalein (Panreac)
Ethanol (Panreac)
Potassium hydroxide (Panreac)
Powdered zinc (d'Hemio)
Hydrogen peroxide (Prolabo)
Glacial acetic acid (Probus)
Ascorbic acid (Merck)
Distilled water

Material For
Volume measurement
Preparation and study of samples
Blood extraction
Also:
Analytical balance
Centrifuge
Oven
Refrigerator
Observation chamber
Pressure roller

Tests Using Tolidine:

1. Collection: We obtained blood specimens by means of venipuncture;

2. Reagent preparation: We added 1.6 g of o-tolidine base to 40 mL of absolute ethanol. To this we added 30 mL of glacial acid and 30 mL of distilled water.

3. Specimen preparation: We prepared blood solutions. Concentration is expressed in milliliters of blood per total volume in milliliters. We added 1 mL of the blood sample to a test tube, followed by 9 mL of distilled water, for a final solution concentration of 1:10. We diluted 1 mL of 1:10 solution to 10 mL to yield a corresponding 1:100-concentration solution. We used the same procedure, in turn, to obtain sample concentrations of 1:1000, 1:10000, and 1:100000.

4. Acid solution preparation: Using the normal concentration of lemon juice in ascorbic acid, 0.38 mg/mL (Jimenez et al. 1994), we prepared a base aqueous solution to test the bloodstain and to obtain diluted solutions with a smaller concentration of the contaminant, from 2.e-3 M to 2.e-7 M.

5. Blood-specimen preparation with the addition of the contaminant: Each test tube sample contained 1 mL of the blood solution and 1 mL of the different ascorbic acid solutions.

6. Bloodstain preparation on semiporous filter paper: We applied five drops of the sample on filter paper.

7. Study of the presumptive test: We added two drops of reagent to the samples (fresh solution [0.1 mL], dried stain, and print), and then if no color change was observed, we added two drops of a 3 percent solution of hydrogen peroxide.

> 7.1. *Control test:* We ensured that no positive reactions were caused by the contaminant.
>
> 7.2. *Analysis of liquid, stain, and print samples:* We obtained prints by dampening filter paper with distilled water and applying pressure over the stain. The test was performed on the print leaving a stain on the paper.

Tests Using Tetramethylbenzidine, Leucomalachite Green, and Phenolphthalein:
We repeated the procedure previously described using the reagents tetramethylbenzidine, leucomalachite green, and phenolphthalein, but the tests were only performed on stains on filter paper. We prepared the reagents as described by Eckert and James (1989).

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Results

Tests Using Tolidine:
The results we obtained are shown in Table 1. This table was used to construct Figures 1A, 1B, and 1C.

Tests Using Tetramethylbenzidine, Leucomalachite Green, and Phenolphthalein:
The results we obtained are shown in Table 2. Figure 2 provides a comparison of the effectiveness of the reagents in samples contaminated by ascorbic acid.

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Evaluation of the Results

When added to a blood sample, ascorbic acid gives rise to a false negative upon application of the presumptive test using tolidine as a reagent. The effect of the contaminator may vary as follows:

- With the fresh solution samples, the first negative readings corresponded to samples of 1:2000 blood solution.
- In the case of 1:200000 blood solution samples, we observed negative readings throughout the concentration interval when using the contaminant.
- In the case of dried stain samples, our results indicate that the contaminant does not interfere with the outcome of the test when using blood concentrations in the range of 1:2 to 1:20000.

- In the print samples, we noted no interference with the reaction for blood concentrations in the 1:2 to 1:2000 interval.
- We recorded negative results after performing tests with samples at a concentration of 1:20000 in blood.
- We performed no tests on 1:200000 specimens because, on applying the assay to a print without any contaminant, the outcome was found to be negative already.

The second experiment we performed demonstrates the possibility of obtaining false negatives with reagents frequently used in presumptive tests. Just as false positives are sometimes encountered, our tests affirm that false-negative results may be obtained as a result of sample contamination.

We proved that there are differences in sensitivity with respect to the action of the contaminant among different reagents. Following analysis of the tests performed on stains on paper, we found that false negatives were detected using tetramethylbenzidine with low-concentration blood samples (1:400000), whereas o-tolidine and leucomalachite green produced the same with samples that were slightly more concentrated (1:200000) and phenolphthalein gave false negatives in samples concentrated at 1:2000.

One possible explanation is that the reducer competes for oxygen in the reagent and prevents oxidation. Alternately, the ascorbic acid may also reduce the reagent after it has been oxidized by the hydrogen peroxide, thus preventing the characteristic color from appearing because of the breakdown of the reagent and its rapid disappearance.

The presence of ascorbic acid may not be the only cause of false results. It is possible for a bloodstain to go unnoticed if it has had sufficient contact with a product with a high reduction strength (detergents and foods). Evidence examiners should also consider that a variety of circumstances, such as washing, rain, heat, and time, may reduce the concentration of blood in the sample, with small amounts of contaminant being sufficient to give rise to a false negative in the presumptive test. Examiners may, therefore, encounter stains that look like blood, but these stains would not be recognized as such in a presumptive test. This would give rise to a false negative in an otherwise reliable presumptive test, with the result that important evidence may be lost.

The frequency with which contamination-related problems are encountered is unknown, but such problems do exist. Therefore, it is impossible to enumerate the specific circumstances in which special care should be taken to avoid such problems. As we noted in the introduction, the important point is that presumptive tests performed on a bloodstain may give rise to a negative result, thereby truncating subsequent tests.

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Summary

We studied false-negative results in bloodstain presumptive tests using blood samples to which contaminating substances were added. As a result, we found that a reduction compound (ascorbic acid) added to the blood sample may give rise to a false-negative result for the test. This occurred regardless of the type of sample used (liquid, stain, or print),

although different degrees of sensitivity were observed.

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Critical Revision of Presumptive Tests for Bloodstains

Table 1

Tolidine Test With Samples That Contain Blood and Ascorbic Acid

Variable			Ascorbic Acid Concentration (In Sample) (M)																				
Blood solution (mL blood/ mL solution)	Sample blood concentration (mL blood/ mL solution)	Sample	0 (control test)			1.10 e-3			0.55 e-3			1.10 e-4			1.10 e-5			1.10 e-6			1.10 e-7		
0 (control test)	0 (control test)	Fresh solution	▨	▨	▨	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Dried stain	▨	▨	▨	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Print	▨	▨	▨	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
1	1:2	Fresh solution	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Dried stain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Print	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
1:10	1:20	Fresh solution	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Dried stain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Print	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
A	B	Fresh solution	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Dried stain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Print	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
C	D	Fresh solution	+	+	+	−	−	−	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Dried stain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Print	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
E	F	Fresh solution	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	+	+	+	+	+	+
		Dried stain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		Print	+	+	+	−	−	−	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
G	H	Fresh solution	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Dried stain	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Print	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
H	I	Fresh solution	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
		Dried stain	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Print	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
J	K	Fresh solution	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
		Dried stain	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Print	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
I	L	Fresh solution	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
		Dried stain	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Print	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
M	N	Fresh solution	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
		Dried stain	+	+	+	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−	−
		Print	−	−	−	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨

Key to blood solution concentrations:

A = 1:100
B = 1:200
C = 1:1000
D = 1:2000
E = 1:10000

H = 1:200000
I = 1:400000
J = 1:300000
K = 1:600000
L = 1:800000

F = 1:20000 G = 1:100000	M = 1:500000 N = 1:1000000

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Critical Revision of Presumptive Tests for Bloodstains

Figure 1
Blood Concentration Analysis

Figure 1A
Fresh Solution

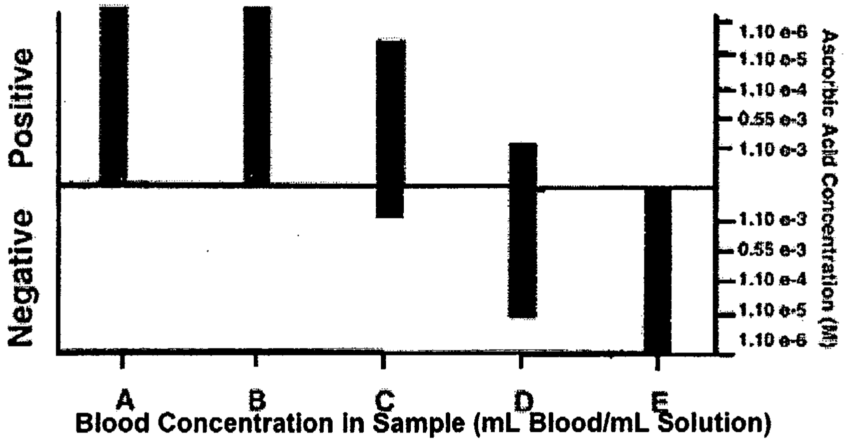
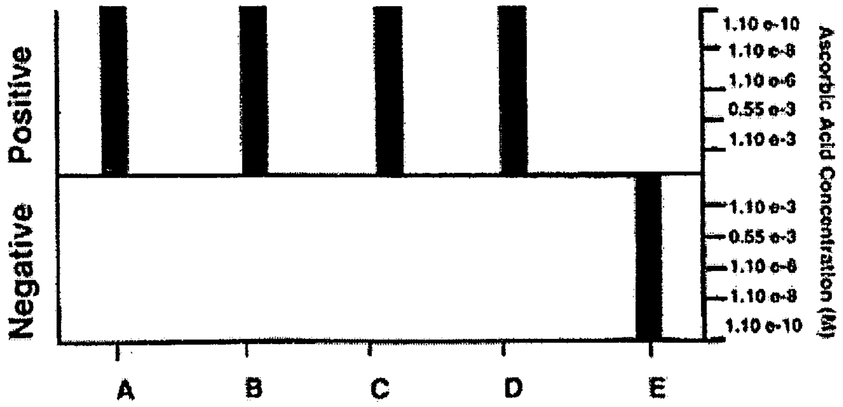
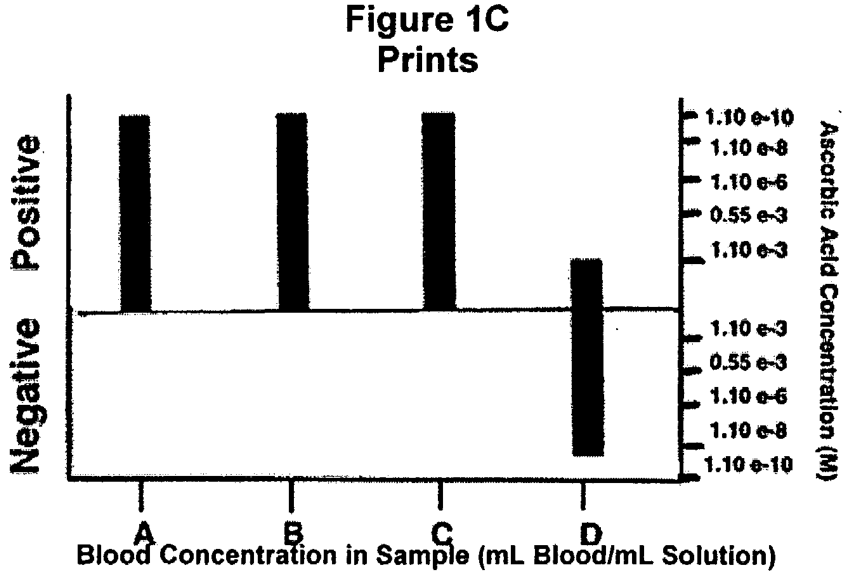


Figure 1B
Dried Stain



Blood Concentration in Sample (mL Blood/mL Solution)



Key to blood solution concentrations:

A = 1:20
B = 1:200
C = 1:2000
D = 1:20000
E = 1:200000

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Critical Revision of Presumptive Tests for Bloodstains

Table 2

Presumptive Test With Samples That Contain Blood and Ascorbic Acid

Reagent	Blood Concentration in Samples (mL Blood/mL Solution)				
	A	B	C	D	E
0-Tolidine	+	+	+	−	−
Tetramethylbenzidine	+	+	+	+	−
Leucomalachite Green	+	+	+	−	−
Phenolphthalein	+	−	−	−	−

Key to blood solution concentrations:

A = 1:200
B = 1:2000
C = 1:20000
D = 1:200000
E = 1:400000

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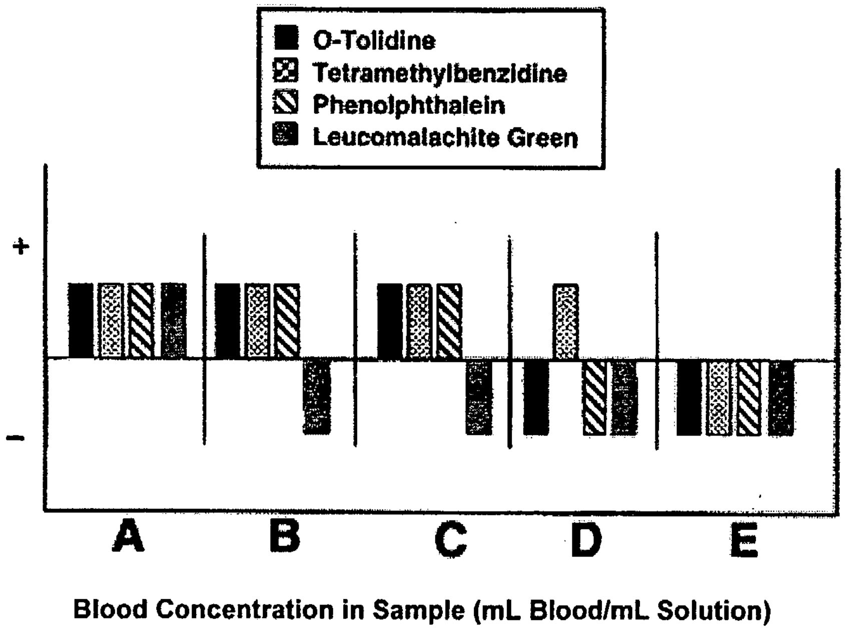
Critical Revision of Presumptive Tests for Bloodstains

Figure 2

Effectiveness of Reagents in Samples Contaminated by Ascorbic Acid



Key to blood solution concentrations:

A = 1:200
B = 1:2000
C = 1:20000
D = 1:200000
E = 1:400000

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APPENDIX C (RELATED PROCEEDINGS)

There are no related proceedings.